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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/242,561 02/19/99 SATO

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EXAMINER

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KENYON & KENYON
1025 CONNECTICUT AVENUE NW
WASHINGTON DC 20036-5405

FORMAN, B

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/242,561

Applicant(s)

SATO, YOSHIHIRO

Examiner

BJ Forman

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

Art Unit: 1655

DETAILED ACTION

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-12 and 16-20 are indefinite because the claims are drawn to a method for retaining a minute droplet on a substrate but the claims do not recite active and positive. "Retaining" is a property of the "separating into two phases". "Retaining" is not an active method step and therefore it is unclear what method steps are required to perform the claimed method. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded. *Ex parte Erlich*, 3 USPQ2d 1011 at 6. It is suggested that the claims be amended to recite active and positive method steps e. g. applying, positioning.

b. Claims 1-20 are indefinite in the recitation "liquid separating into two phases" because it is a *non sequitur* to the preamble recitation of "retaining the minute droplet". It is suggested that the claims be amended in the last line of Claim 1 to recite "separating into two phases and thereby retaining the minute droplet on the substrate". The claims are further indefinite because "separating into two phases" lacks proper antecedent basis in "layer of liquid". It is suggested that Claims 1 and 2 be amended to combine the two claims into one claim.

Art Unit: 1655

c. Claim 3 is indefinite in the recitation “minute droplet is shot into said liquid layer coated over the surface of said substrate from a surface of said liquid layer” because “coated over the surface of said substrate” is redundant and superfluous and because the syntax is confusing. Therefore it is unclear where the droplet is “shot” from and “shot” to. It is suggested that the claim be amended to clarify e.g. “minute droplet is shot into said liquid layer”.

d. Claim 5 is indefinite because it is unclear at what step in the method step of Claim 1 “the surface of said liquid layer is covered” and because “the surface of said liquid layer” lacks proper antecedent basis in Claim 1. It is suggested that the claim be amended to recite a method step for covering and to delete “ the surface of”.

e. Claim 6 is indefinite in the recitation “in the vicinity of said minute droplet” because “vicinity” is a non-specific relational term. It is suggested that the claim be amended to recite “adjacent to said minute droplet” or to delete “in the vicinity”. The claims are further indefinite because the recitation “another aqueous solution” lacks proper antecedent basis in Claim 2. It is suggested that the claim be amended to recite “another aqueous droplet”.

f. Claims 8-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Method steps for “effecting a reaction”. The claims are drawn to “A reacting method” but the claims do not recite the essential steps of reacting. It is suggested that the claims be amended to recite the omitted steps.

g. Claim 10 is indefinite in the recitation “a site the contact of said minute droplet” because “the contact” lacks proper antecedent basis in Claim 9. The claim is further indefinite because it is unclear whether the “site of contact” refers to the substrate, the liquid layer or the covering. It is suggested that the claims be amended to clarify e.g. insert “on the substrate” after “droplet”.

Art Unit: 1655

h. Claim 11 is indefinite because the recitation "the contact site" lacks proper antecedent basis in Claims 9. It is suggested that the claim be amended to depend from Claim 10.

j. Claim 19 is indefinite in the recitation "the surface of said liquid layer" because "the surface" lacks proper antecedent basis in Claim 2. It is suggested that the claim be amended to delete "the surface".

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 4-7 and 17-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brown et al. (U.S. Patent No. 5,807,522, 15 September 1998).

Regarding Claim 1, Brown et al. disclose a method for retaining a minute droplet on a substrate said method comprising retaining the minute droplet in a layer coated over a surface of said substrate wherein said minute droplet is in contact with said substrate and said minute

Art Unit: 1655

droplet and said liquid separate into two phases (Column 7, lines 47-54). Additionally Brown et al. teach the layer coated over the surface of the substrate is hydrophobic polymers, lubricants, and films (Column 7, lines 50-54) and the layer is applied by spraying or coating uncured polymers onto the substrate (Column 12, lines 11-12). It would have been known to one of ordinary skill in the art that it is an inherent property of hydrophobic polymers, lubricants, and films that they would be applied as liquids.

Regarding Claim 2, Brown et al. disclose said minute droplet is aqueous and said layer coated over the surface of the substrate is oily i.e. hydrophobic lubricant (Column 7, lines 51-52). It would have been known to one of skill in the art that lubricants have the inherent property of being oily.

Regarding Claim 4, Brown et al. disclose the surface of said substrate has water repellency i.e. hydrophobic (Column 7, lines 47-54).

Regarding Claim 5, Brown et al. disclose the surface of said substrate is covered with a covering i.e. cover slip (Example 1, Column 16, lines 61-62).

Regarding Claim 6, Brown et al. disclose another aqueous solution is retained in the vicinity of said minute droplet (Example 1, Column 16, lines 57-61).

Regarding Claim 7, Brown et al. disclose the surface of said substrate and said minute droplet is covered with a covering i.e. cover slip (Example 1, Column 16, lines 61-62).

Regarding Claims 17 and 18, Brown discloses the surface of said substrate has water repellency i.e. hydrophobic (Column 7, lines 47-54).

Regarding Claims 19 and 20, Brown disclose the surface of said substrate is covered with a covering i.e. cover slip (Example 1, Column 16, lines 61-62). The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Brown et al. is silent with regard to the liquid property of hydrophobic polymers, lubricants and films the and oily property of lubricants. However, the liquid and oily properties recited in Claims 1-7 and

Art Unit: 1655

16-20 are deemed to be inherent in the hydrophobic polymers, lubricants and films in Brown et al. because one of ordinary skill in the art would have known that hydrophobic polymers, lubricants and films are applied as liquids and would have known that lubricants are oily. The burden is on applicant to show that the claimed liquid and oily properties are either different or non-obvious over that of Brown et al.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 8, 9 and 12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Brown et al. (U.S. Patent No. 5,807,522, 15 September 1998).

Regarding Claim 8, Brown et al. teach a reaction method comprising the steps of retaining a minute droplets on a coated substrate wherein said minute droplet and coating separate into two phases (Column 7, lines 46-54); covering the surface of said liquid layer with a covering (Example 1, Column 16, line 62); and effecting a reaction in said minute droplet (Example 1, lines 57-65).

Regarding Claim 9, Brown et al. teach the minute droplet is a DNA-containing aqueous droplet (Column 17, lines 46-50 and Example I) and the surface of said substrate is oily i.e. hydrophobic (Column 7, lines 36-38).

Art Unit: 1655

Regarding Claim 12, Brown et al. teach the layer coated on the substrate is of a thickness less than 100 μ m (Column 12, line 10).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 3 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent No. 5,807,522, 15 September 1998) as applied to claim 1 above, and further in view of Blanchard (U.S. Patent No. 6,028,189, 22 February 2000).

Regarding Claim 3, Brown et al. teach the method for retaining a minute droplet on a substrate. Brown et al. do not disclose said minute droplet is shot into said hydrophobic layer. However, Blanchard teaches a method for retaining a minute droplet on a substrate wherein the droplet is shot into said hydrophobic layer on the substrate (Column 11, lines 60-64).

Regarding Claim 16, Brown et al. do not teach said minute droplet is shot into said hydrophobic layer (Column 8, lines 1-9 and Fig. 2C). However, Blanchard teaches the method for retaining a minute droplet on a substrate wherein the droplet is shot into said hydrophobic layer (Column 11, lines 60-64 and Fig. 1 and 3).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Brown et al. with the method of Blanchard because the skilled practitioner would have been motivated with a reasonable expectation of success to modify the Brown et al. method for tapping a minute droplet onto a

Art Unit: 1655

substrate with the Blanchard method for shooting a minute droplet into a hydrophobic layer covering a substrate for the expected benefit of speed of droplet delivery as taught by Blanchard (Column8, lines 54-55).

10. Claims 10 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent No. 5,807,522, 15 September 1998) as applied to claim Claims 8-10 above, and further in view of Sambrook et al. (Molecular Cloning: A laboratory Manual, 2nd Ed., 1992).

Regarding Claim 10, Brown et al. do not teach the droplet contact site has an enzyme adsorption preventing agent. However, Brown et al. teach the reactions method wherein the methods include nucleic acid hybridization assays. The skilled practitioner in the art would have known that hybridization assays utilize SDS enzyme adsorption preventing agent as taught by Sambrook et al. Sambrook et al. teach that Denhardt's reagent which contains SDS is used in nucleic acid hybridization assays to block non-specific reactions and increase signal-to noise ratios (page 9.48).

Regarding Claim 11, Brown et al. teach the reaction methods wherein the methods include nucleic acid hybridization assays. The skilled practitioner in the art would have known that hybridization assays utilize bovine serum albumin as a blocking agent as taught by Sambrook et al. Sambrook et al. teach that Denhardt's reagent which contains bovine serum albumin is used in nucleic acid hybridization assays to block non-specific attachment of nucleic acids to the surface of the substrate (page 9.47-9.48). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Brown et al. with the teaching of Sambrook et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to use Denhardt's reagent as a blocking agent in the hybridization assay

Art Unit: 1655

taught by Brown et al. because Denhardt's reagent provides the expected benefit of convenience in that it is commercially available and it is a premixed blocking solution.

11. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stimpson et al. (U.S. Patent No. 5,843,651, 1 December 1998) in view of Sambrook et al. (Molecular Cloning: A laboratory Manual, 2nd Ed., 1992).

Regarding Claim 13, Stimpson et al. teach a reaction vessel comprising a transparent lower plate i.e. glass cover slip (Fig. 2B, #34, Column 8, lines 39-40 and 50 Example 5); a spacer having a thickness of less than 0.1 mm (Column 8, lines 33-38); a transparent upper plate (Fig. 2B, #32, and Column 8, lines 39-40); and reaction vessel containing a solution in a space surrounded by the spacer (Fig. 2B, #46 and Column 8, lines 35-36). Stimpson et al teach the spacer is made of double stick tape having a thickness of less than 0.1mm but they do not discuss a spacer of 0.05mm or less.

Regarding Claim 14, Stimpson et al. teach the spacer is made of double stick tape (Column 8, lines 33-34).

Regarding Claim 15, Stimpson et al. teach the solution contact site i.e. glass cover slip is coated with casein to block non-specific interactions between the sample and the glass surface (Example 5, Column 5, lines 27-30). Stimpson et al. do not teach bovine serum albumin coating however it was known in the art that casine and bovine serum albumin block non-specific interactions between the sample and the glass surface as taught by Sambrook et al. (page 9.48).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus of Stimpson et al. with the teachings of Sambrook et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated with a reasonable expectation of success to modify the blocking of

Art Unit: 1655

non-specific interaction on the glass surface by coating with casein to the closely related bovine serum albumin for the expected benefit of higher signal-to-noise ratio for the later as taught by Sambrook et al. (page 9.48, paragraph 5, lines 19-20). The skilled practitioner in the art would have been further motivated with a reasonable expectation of success to use a spacer wherein the spacer is double stick tape of less than 0.1mm thickness for the expected benefit of convenience, ease of use, commercial availability, and compressible properties.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
March 6, 2000

SE Forman
SE Forman
Principal Examiner